## REMARKS

The Office Action of November 30, 2004 presents the examination of claims 1-25. The present paper amends claim 1 to insert the recitations of claim 2, which in turn is canceled. Claims 26-34 are canceled, being directed to subject matter deemed a separate invention by the Examiner and constructively not elected due to failure to present such claims at the beginning of prosecution. Applicants reserve the right to file an application directed to the canceled subject matter as provided by 35 USC §§ 120 and 121.

Rejections under 35 U.S.C. § 112, first paragraph

*Written Description*

The Examiner has maintained the rejection of claims 1-8 and 21 under 35 U.S.C. § 112, first paragraph, for alleged lack of written description of the invention. This rejection is respectfully traversed. Reconsideration and withdrawal thereof are requested.

The Examiner mistakenly requires that the Applicant limit their claims to subject matter that has actually been reduced to practice. It is not and has never been the law in the United States that an Applicant must restrict his claims to working examples actually reduced to practice. *See, e.g. In re Rasmussen,* 221 USPQ 323 (CCPA 1981); *In re Koller, Hartl & Kirchner,* 204 USPQ 702 (CCPA 1980). Indeed working examples are not at all required for a disclosure to adequately support a claim. *In re Strahilevitz*, 212 USPQ 561 (CCPA 1982).

In the present instance, the Applicants have named a number of species of grasses from which the protein of the instant invention may be obtained. See, page 9, lines 26-30, disclosing that the protein of the invention may be obtained from grasses of the species *Imperata cylindrica* (which isolation constitutes the working example), *Lolium perenne, Pheleum pretense* and *Cynodon dactylon* and from grasses of related genera.

The Examiner bears a burden of demonstrating that the protein of the invention would not be obtainable from these species, and further must accept as true statements made in the specification, absent any sound reasoning or evidence to the contrary. *In re Marzocchi & Horton,* 169 USPQ 367 (CCPA 1971). The Examiner has not provided any such sound reasoning or evidence that the statements in the specification as to from which plants the protein

of the invention can be obtained is incorrect. In fact, the specification provides some evidence of the correctness of this statement; Figure 3 shows an immunoblot and ELISA tests of extracts from the named plants using serum from allergic patients, showing the presence of a 67 kDa IgE binding protein. Accordingly that description must be taken as true and it serves to adequately support the present breadth of the claims. Therefore, the instant rejection must be withdrawn.

*Enablement*

Claims 1-8 and 21 also stand rejected under 35 U.S.C. § 112, first paragraph, for alleged lack of enablement by the specification. This rejection is respectfully traversed. Reconsideration and withdrawal thereof are requested.

In particular, the Examiner asserts that the disclosure of inhibition of anthrax toxin activity by the presently claimed protein *in vitro* is insufficient to support an asserted utility of inhibition of anthrax toxin activity *in vivo*. The Examiner raises several questions about how a preincubation step would be accomplished and how an allergic patient would be treated, all of which are irrelevant to the question of enablement.

The Applicants' burden in writing the specification is merely to establish, by a preponderance of the evidence, not beyond reasonable doubt or even clear and convincing evidence, that the protein in question would have the utility asserted and so that the use of the invention is enabled. To this end, the specification quite clearly demonstrates that the protein of the invention is able to inhibit anthrax toxin *in vitro*. Furthermore, the *in vitro* test is one performed on cultured cells in the presence of blood serum proteins (see Example 7). Thus, the protein of the invention can likely retain its activity in circulation, and is effective in preventing anthrax toxicity to mammalian cells.

One of ordinary skill in the art would be able to administer the protective protein of the invention in a suitable manner. The Examiner is reminded that the standard for utility is quite low. It is not necessary that each and every person be treatable by the invention. A utility in which a population at high risk for anthrax toxin exposure is treated prophylactically[1] would be

[1] For example, the equipping of soldiers expecting to encounter nerve agents in battle with syringes of atropine is well-known.

sufficient to meet the requirements of 35 USC § 101. This would address the Examiner's question about "preincubation". Furthermore, if as the Examiner suggests, it is well-known that IgE antibody in the serum of grass-allergic subjects would interfere with the prophylaxis, then either a higher dose would be given, or such subjects simply would not be treated. Neither of the scenarios imagined by the Examiner impair the asserted utility so badly that it does not meet the requirements of 35 USC § 101.

Furthermore, the administration of proteins as antitoxins is well-known in the prior art. For instance, protein antivenoms are routinely formulated and administered to snake-bite victims. The specification provides an indication of the concentration of the protein of the invention effective in inhibiting anthrax toxin, and is it within the skill of the practitioner of pharmacology to perform known pharmacodynamic experiments based on this information to arrive at an effective *in vivo* dose.

Still further, an *in vitro* test may be sufficient to establish a therapeutic use for a novel compound, and it is contrary to the intent of the patent laws to require complete reduction to practice of therapeutic use, i.e. an example of actual therapy, as such would delay disclosure of the invention, rather than promote it. *See, In re Bundy,* 209 USPQ 48 (CCPA 1981).

For all of the above reasons, Applicants submit that the present specification is sufficiently enabling of how to use the claimed invention to meet the requirements of the statute, and the instant rejection should be withdrawn.

Rejections over prior art

Claims 1-8 and 21 stand rejected under 35 U.S.C. § 102(a) as anticipated by Bijli et al. (2003) or under 35 U.S.C. § 102( b) as anticipated by Bijli et al. (2002), or under 35 U.S.C. § 102(b) as anticipated by Verma et al. (2000). Each of these rejections is respectfully traversed. Reconsideration and withdrawal thereof are requested.

As to Bijli (2003) and (2002), the Examiner mischaracterizes the disclosure of these papers as showing an isolated protein.

Bijli (2003) relates to the storage stability of crude extracts of allergens from *Imperata cylindrica. See,* page 66, in the first column, under "Collection of pollen and preparation of

extract", where defatting and ether extraction of the pollen are the only steps described. The SDS-PAGE characterization of the extracts shows that there are 37 different protein bands ranging in molecular weight from 12 to 110 kDa in the extracts. *See,* page 66 at the bottom of the second column and Figure 1.

In contrast, the present specification describes purification of a 67 kDa protein using hydrophobic interaction chromatography. The resulting protein is sufficiently purified as to present only a single band on SDS-PAGE analysis. *See,* page 10, lines 1-6 of the specification and Example 4 (purification) and Figures 1(b) and 4 (SDS-PAGE).

Thus, the present invention is distinct from what is disclosed by the Bijli (2003) reference, and the rejection of claims 1-8 and 21 as anticipated by this paper should be withdrawn.

Figure 1(a) in Bijli (2002) also does not show a purified protein, but rather a number of bands (at least 12) appear in SDS-PAGE analysis of the extracts prepared. Thus, Bijli (2002) does not describe any isolated protein of 67 kDa. This result also should be compared with that of Figure 1(b) and Figure 4 in the instant specification, which plainly show a single band on SDS-PAGE. Accordingly, the rejection of claims 1-8 and 21 as anticipated by this reference should be withdrawn.

The Examiner's requirement for "side-by-side" comparison and presentation of evidence in declaration form is inappropriate in the above instances. The data showing the difference in purification between the instantly claimed invention and the extracts disclosed in the references are self-evident.

As to Verma (2000), Applicants provide attached a Declaration of Naveen Arora, which shows that the isolated protein of the present invention was purified by hydrophobic interaction chromatography (see page 10, lines 1-6 of the specification and Example 4) and subjected to amino-terminal sequencing with the result that the sequence D-[QT]-P-Y-S-E-K was obtained. In contrast, Verma et al. purify their protein to a single band by SDS-PAGE anaylsis using ion exchange chromatography, and find that the amino terminus is blocked and consequently no sequence was obtained. *See,* the legend to Figure 1 (purification) and the top of column 1 on page 255 (sequencing result). Thus it is quite plain that the protein obtained by Verma et al. and

that of the present invention are distinct. Accordingly, the rejection of claims 1-8 and 21 as anticipated by Verma et al. should be withdrawn.

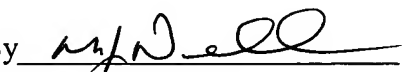
Applicants submit that the above evidence firmly establishes that the protein of the invention is different from that described in Bijli (2003), Bijli (2002) and in Verma (2000). Therefore the rejections made over each of these references should be withdrawn.

The present application well-describes and claims patentable subject matter. The favorable action of allowance of the pending claims and passage of the application to issue is respectfully requested.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Mark J. Nuell (Reg. No. 36,623) at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

Dated: February 6, 2006

Respectfully submitted,

By 

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Attachment: Declaration Under 37 C.F.R. § 1.132